510(k) Summary

Proprietary Name:	VariAx Distal Radius Plating System Line Extension
Common Name:	Bone Plates Bone Screws
Classification Name and Reference:	Single/multiple component metallic bone fixation appliance and accessories 21 CFR §888.3030 Smooth or threaded metallic bone fixation fastener 21 CFR §888.3040
Regulatory Class:	Class II
Product Codes:	HRS: Plate, Fixation, Bone HWC: Screw, Fixation, Bone
Sponsor:	Stryker Leibinger GmbH & Co.KG
Contact Person:	Elijah N. Wreh Regulatory Affairs Specialist 325 Corporate Drive Mahwah, NJ 07430 elijah.wreh@stryker.com Phone: 201-831-5691 Fax: 201-831-4691
Date Prepared:	December 23, 2013

Description

This Traditional 510(k) submission is being supplied to the U.S. FDA to obtain authorization to market a line extension to the VariAx Distal Radius Plating System, which was cleared in K040022, as the Universal Distal Radius System. The VariAx Distal Radius Plating System Line Extension consists of multiple internal fixation plates in varying lengths and widths. The portfolio of plates is being extended to include new plate width (intermediate) and new plate length (extrashort).

The plates will be used with the VariAx locking screws, non-locking screws, locking pegs, and partially threaded screws previously cleared in K040022, K080667, and K132502. The subject components will be available sterile and non-sterile.

Intended Use

The VariAx Distal Radius Locking System including the XXL Volar Distal Radius Plates is intended for internal fixation of small bone fractures, primarily including distal radius fractures.

Indications for Use

Indications include:

- compression fractures
- intra-articular and extra-articular fractures
- displaced fractures

Following additional indications apply only for the XXL Volar Distal Radius Plates: Osteotomies, non-unions, and malunions.

Substantial Equivalence

The subject plates being added to the VariAx Distal Radius Plating System are substantially equivalent to the VariAx Distal Radius Plating System (K040022) and the VariAx Distal Radius Line Extension of XXL Plates (K100271) in regards to intended use, design, materials, and operational principles for use for internal fixation for fractures and reconstruction of the small bones in the distal radius.

Non-Clinical Test

Non-clinical laboratory testing was performed on the worst case subject plates to determine substantial equivalence. Testing demonstrated that the subject plates being added to the VariAx Distal Radius Plating System are substantially equivalent to the currently marketed predicate devices. The following testing was performed "Standard Specification and Test Method for Metallic Bone Plates as per ASTM F382 – 99: 2008."

Clinical Testing

Clinical testing was not required for this submission.

Conclusion

The subject devices which are being added to the VariAx Distal Radius Plating System are substantially equivalent to the predicate devices identified throughout this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 24, 2014

Stryker Leibinger GmbH & Co. KG
Mr. Elijah N. Wreh
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K133974
Trade/Device Name: VariAx Distal Radius Plating System Line Extension
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: February 27, 2014
Received: February 28, 2014

Dear Mr. Wreh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if Known): K133974

Device Name: VariAx Distal Radius Plating System Line Extension

The VariAx Distal Radius Locking System including the XXL Volar Distal Radius Plates is intended for internal fixation of small bone fractures, primarily including distal radius fractures.

Indications for Use:

- compression fractures
- intra-articular and extra-articular fractures
- displaced fractures

Following additional indications apply only for the XXL Volar Distal Radius Plates:

Osteotomies, non-unions, and malunions.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices